JAN 19 2006

K053171

11.0 Premarket Notification [510(k)] Summary of Safety and Effectiveness

Submitter	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, Utah 84095-2416 USA
Establishment Registration Number	1721504
Contact Person(s)	
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Date Prepared	September 30, 2005
Name of Medical Device	Merit *Impress* Radiology Catheter
Classification Name:	Catheter, Intravascular, Diagnostic (21 CFR 870.1200)
Common/Usual Name:	Diagnostic Catheter
Trade/Proprietary Name:	Merit *Impress* Radiology Catheter
Device Classification	
Panel:	Cardiovascular
Device Class:	Class II
Product Code:	74 DOQ
Regulation Number:	21 CFR 870.1200
Predicate Device Identification	
Predicate 1.	
Device Brand Name	Performa® Diagnostic Radiology Catheter
Classification Name	Catheter, Intravascular, Diagnostic (21 CFR 870.1200)
Device Class	Class II
Classification Panel Number	870 Cardiovascular Devices
Product Code	DOQ
Clearance Status	K000659

Merit Medical Systems, Inc.
Merit Impress™ Radiology Catheter
PREMARKET NOTIFICATION [510(k)]
CONFIDENTIAL
510(k) Summary (per 21 CFR 807.92)

Manufacturer	Merit Medical Systems
Registration Number	1721504

Predicate 2.

Device Brand Name	AngioDynamics Inc., Soft-VU® Omni Flush™
Classification Name	Radiology Catheter Catheter, Intravascular, Diagnostic (21 CFR 870.1200)
Device Class	Class II (Performance Standards)
Classification Panel Number	870 Cardiovascular
Product Code	DQO
Clearance Status	K001578
Manufacturer	AngioDynamics Inc.
Registration Number	1319211

Device Description

Merit's *Impress* consists of a shaft with molded hub and an overmolded segment at the proximal end of the device. The shaft is initially available in a wirebraid reinforced shaft. The distal tip is tapered for even high volume flow and dispersion of the contrast media, and flexible to minimize the potential for vessel trauma.

Intended Use

Angiography catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Angiographic catheters with marker bands may also be used for anatomical measurements.

510(k) Summary (per 21 CFR 807.92)

Summary of Characteristics in Relation to Predicate Device(s)

Does the new device have the same indication statement as the predicate device?

Yes.
The Merit Impress™ Radiology Catheter is intended for use in delivering radiopaque media to slected sites in the vascular system in conjunction with routine diagnostic procedures.

Does the new device have the same technological characteristics, e.g., design, materials, etc. as the predicate device?

Yes.
The Merit Impress™ Radiology Catheter employs a similar method of operation and design as compared to the predicate devices. Both the new and predicate devices consist of a proximal hub, shaft and distal tip. Both the new and predicate devices are comprised of similar materials and serve as passive conduits for the delivery of contrast media under high pressure.

Are the descriptive characteristics precise enough to ensure equivalence to the predicate device?

No.
Bench testing was conducted on the *Impress* in order to establish substantial equivalence.

Are performance data available to assess effects of the new device as compared to the predicate device?

Yes.
Performance testing was conducted according to protocols based on international standards as well as Merit's in-house protocols. Where performance could affect the safety or effectiveness of the *Impress*, comparison with the predicate devices was conducted, and conformance to validated criteria was confirmed.

Does performance data demonstrate equivalence?

Yes.
Performance data demonstrates that the *Impress* is substantially equivalent to the predicate devices.

Conclusion: "Substantial Equivalence" Determination
Based on CDRH's substantial equivalence decision tree, the *Impress* is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2006

Merit Medical Systems, Inc.
c/o KEMA Quality B.V.
4377 County Line Road
Chalfont, PA 18914
Attn: Mr. J.A. Van Vugt

Re: K053171
Merit Impress Radiology Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II
Product Code: DQO
Dated: December 22, 2005
Received: December 23, 2005

Dear Ms. Erskine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vickers

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION(S) FOR USE STATEMENT *

510(k) Number (if known): K053171

Device Name: Merit Impress ™ Diagnostic Radiology Catheter

Indications for Use:

Angiography catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Angiographic catheters with marker bands may also be used for anatomical measurements.

Prescription Use ___X___ (Part 21 CFR 901 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart O)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mahney
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053171